The Information Study/ QRI+INCLUSION SWAP: A guide

Information Study Research team

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What is the Information Study?

The QuinteT/Information study team are supporting recruitment to the SCC-AFTER study. QuinteT is a research group of trials researchers from the University of Bristol. A QuinteT Recruitment Intervention (QRI) is an intervention designed to be integrated within a randomised controlled trial (RCT) with the aim of optimising recruitment and informed consent. The goal is that all eligible patients have the opportunity to make an informed choice about participation. Within SCC-AFTER we've embedded an INCLUSION-SWAP, (a Study Within A Project) with an emphasis on including people who have traditionally been excluded from research. This includes people who are older and frailer, as they are an important sub-group among those with cutaneous squamous cell carcinoma.

There are three key sets of data collected for the Information Study in SCC-AFTER:

Audio-recordings of recruitment discussions

Screening data

Interviews

Audio-recording recruitment discussions: This will involve audio-recording recruitment discussions that you have with potential participants about SCC-AFTER. More details on how to do this are shared in the next few pages.

Screening log data: This will involve recording screening and recruitment data. For more details of how to enter this data please see the Database Guide.

Interviews:

- **Health and research professional interviews:** You may be invited to take part in an interview with the Information Study researcher. These will last 45 minutes and be over the telephone or MS Teams (whichever is most convenient for you).
- **Patient interviews:** You will also be asked to invite patients, who have declined participation in the overall study, to an interview with the Information Study researcher. If they agree, you as the recruiter, can pass on their contact details to the Information Study researcher. Interviews will last 30-45 minutes and be over the phone.

Patients will be sent a copy of the SCC-AFTER PARTICIPANT INFORMATION SHEET (PIS) in advance or given the PIS in an initial face to face discussion. Patients will be provided with sufficient time to read the information, ask any questions, and consider participation in the Information study. The PIS contains information about the Information Study. The PIS explains that potential participants may be asked if their discussions about the study can be recorded and about a potential interview.

For more information about the interviews and audio-recordings please refer to the Health and Research Professionals: Participant Information and Consent Form and the SCC-AFTER protocol.

Consent process

For further information about the consent processes for this information study, please refer to section 17.4.1 of the SCC-AFTER protocol and watch the pre-SIV content. Available here: SCC-AFTER: Panopto. For more details of how to enter this data please see the Database Guide.

Consent process for health and research professionals

All personnel involved in the recruitment of patients for SCC-AFTER at sites who have agreed to take part in the Information Study, will be asked to sign a 'master' consent form, the Health and Research Professionals: Participant Information and Consent Form, which will cover different aspects of the Information Study:

- recordings of recruitment discussions,
- interviews,
- observations of TMG/investigator meetings.

Consent for the Information Study can be provided in either written or verbal form.

- If written consent:
    - This can be countersigned by a colleague locally and a copy of the consent form sent to the Information Study researcher (lucy.wallis@bristol.ac.uk)
- If verbal consent:
    - This can be given to the Information Study researcher over the phone/MS Teams and a copy of the form will be sent to the staff member.

Consent process for patients

Patients will need to sign a separate consent form for the Information Study, while still deciding whether they want to take part in SCC-AFTER. This consent form will cover:

- recordings of recruitment discussions,
- interviews.

Although a patient may decline participation in SCC-AFTER, they may still be keen to do an interview so please do ask patients if they are interested (and receive their consent).

The consent pathway for the Information Study mirrors the consent process for the SCC-AFTER study: written consent can be provided by the patient or by a witness if

the patient cannot sign. The same consent process is used for face-to-face and remote discussions.

Process for receiving consent

Consultation with patient

You could say… "We are trying to learn how best to explain research into your condition. I'd like to record our conversation to help to do that, is that ok with you?"

Patient consents to audio-recording verbally

Use the Verbal Consent to Audio-Recording form to record that the patient is happy for the audio-recording to take place.

You record your discussion with the patient about SCC-AFTER

Ask the patient if they would be willing to give written consent (using the SCC-AFTER Information Study consent form).

This includes written consent for: the audio-recordings of recruitment conversations and being contacted to take part in an interview.

Patients can consent to both recruitment conversation being recorded and interview, consent to only one or decline both.

You upload recruitment discussion (see page 8).

Patient receives one copy of SCC-AFTER Information Study consent form

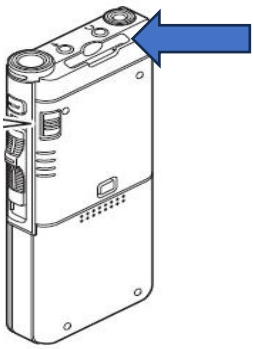
The original SCC-AFTER Information Study consent form is for the research team to be stored in local site file; and one copy to be kept with paper hospital notes or stored electronically.

The original Verbal Consent to Audio-Recording form is for the research team to be stored in local site file; and one copy to be kept with paper hospital notes or stored electronically.

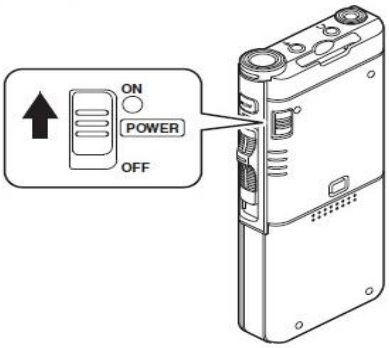
Written consent only needs to be taken once and is then valid for all future recruitment discussions about SCC-AFTER. You can check with the patient each time you meet, that they are still happy to be recorded.

How to use the OLYMPUS recorder

Step 1: INSERT MEMORY CARD: Place the SD memory card in the slot at the top of the recorder by sliding into the slot and pushing to secure.

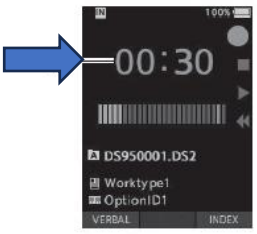


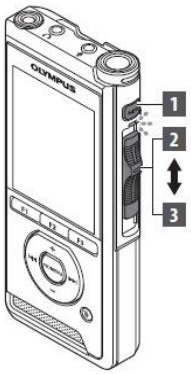
Step 2: TO TURN ON: Turn on the recorder by sliding the **Power** switch on the back of the device to **On**. Enter the four-digit password provided by the Information Study team using the arrows and 'OK/menu' button.



Step 3: TO RECORD: Ensure the SD memory card is in place and that the device is sufficiently charged (see below for instructions).

1. Press the **NEW** button (1) on the side of the recorder to create a new file. [New file] appears in display. And below this shows the new file name.
2. Slide the switch below to **REC** position (2). The LED indictor lights up in red to indicate that recording is in process. The recording elapsed time will be displayed.

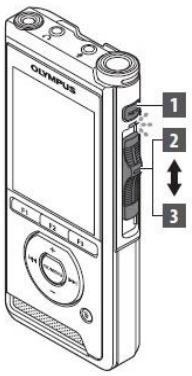




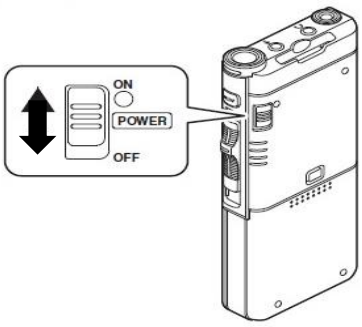
At the start of recording please state:

- Recording for SCC-AFTER
- Date of recording
- Patient identifier: Patient's SCC-AFTER Screening Number
- Staff identifier: SCC-AFTER Site Recruiter ID
- Any companion

Step 4: TO STOP THE RECORDING, move the slide switch to **STOP** position (3).



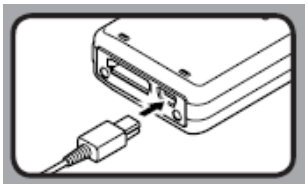
Step 5: TO TURN OFF: Use the **Power** switch on the back of the device and slide it to **Off**. The recordings will be automatically saved onto the memory card.

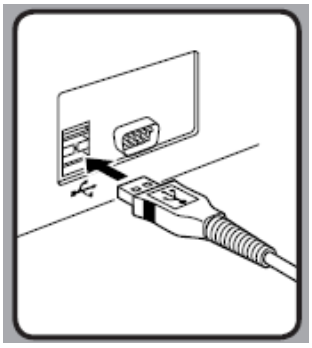


Step 6: RECHARGE RECORDER after each day of recording**.** The battery icon is in the top right of screen. A full bar and “100%” indicate the battery is fully charged.

To recharge:

1. Turn on the computer
2. Connect the USB cable to the USB port of the recorder
3. Connect this USB cable to the USB port of the computer.





[Remote (Composite)] is displayed on the recorder if the USB cable is connected. It will take approximately 2.5 hours to fully recharge.

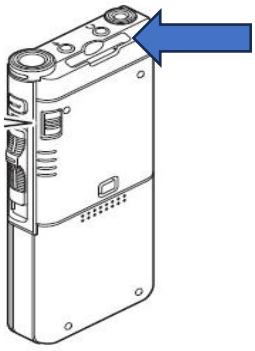
Please Note: Please remember to make a new recording for each patient. So ensure you slide to **STOP** at the end of the appointment and then press **NEW**.

How to transfer recordings from the OLYMPUS recorder to the Information Study team

DO NOT DELETE ANY DATA FROM RECORDERS OR MEMORY CARDS.

All audio files should stay on the recorder and copies should *not* be created on local site computers. The files should be transferred by posting the encrypted memory card to the QRI team at agreed regular intervals. **Your site will be given two digitally encrypted memory cards.**

Step 1: REMOVE MEMORY CARD: With the power switched off, push down lightly on the card in its slot. This will release the card, which can then be removed from the device and placed in its plastic case for posting.



Step 2: INSERT SECOND MEMORY CARD: (See above) Keep the recorder switched off until a new card has been inserted.

Step 3: POST THE MEMORY CARD: Put the memory card in the special delivery envelope. Post the pre-paid special delivery envelop to the Information Study team. The address will already be supplied on the envelope.

The Information Study researcher will download the files and return the memory card.

Please Note: The memory cards are PIN/password protected and only accessible to approved team members. Please contact the Information study team for the PIN/password, if you have not received it.

Information Study practical tips

- The recorder will be set up and ready to use when provided to you. Our intention is to make the recording process as easy as possible.

- Please record discussions you have with patients about SCC-AFTER in person or over the phone (as long as consent has been received).

- If you are having the discussion in person, use the recorder as it is.
- If having the discussion on the phone, there are two options for recording the discussion:

    1. If appropriate, you could use the telephone loudspeaker and record the discussion as above.

    2. You can use an earpiece, supplied by us with the audio recorder, to record the discussion. You can do this by plugging the earpiece into the jack on the left-side of the audio-recorder which is labelled as 'MIC'. (The jack labelled 'EAR' will not record the participant's voice so please do not use). Hold the phone over the ear with the earpiece in it.

- Please record all discussions you have with patients about SCC-AFTER. Obtain verbal consent each time to check they are happy to be recorded, but written consent is only required once.

- We've found in our other work that people have become used to having telephone discussions recorded with organisations for training and monitoring purposes. Therefore, patients are likely to find recording of your recruitment discussions acceptable.

As part of the Information Study, we offer tips, individual and group feedback and training to support you and your colleagues to overcome recruitment difficulties. The more and higher quality data (from screening, audio-recordings of recruitment discussions and interviews) you are able to provide us with, the more and higher quality feedback and guidance we'll be able to give to you.

Please contact us with any queries (see page one for contact details).